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**Re: Comments to the Carcinogenicity Identification Committee (CIC) on Possible Listing of Coumarin**

The Consumer Specialty Products Association<sup>1</sup> offers the following comments on the November 2, 2017 Carcinogen Identification Committee (CIC) meeting of the State's Qualified Experts which is being asked by California's Office of Environmental Health Hazard Assessment (OEHHA) to advise OEHHA on possible listing of coumarin. Coumarin is a fragrance material that is currently being used in a safe and responsible manner in a variety of consumer specialty products.

The Consumer Specialty Products Association (CSPA) believes the available evidence does not support of the listing coumarin as a potential human carcinogen. In addition, CSPA supports the comments submitted by International Fragrance Association North America that details that coumarin has not "been clearly shown through scientifically valid testing according to generally accepted principles to cause ... cancer."

Importantly IARC has evaluated coumarin<sup>2</sup> and classified it as Group 3 and is *not classifiable as to its carcinogenicity to humans*. We call attention to the portion of the definition of Group 3 that states

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<sup>1</sup> CSPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than \$100 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. CSPA member companies employ hundreds of thousands of people globally. Products CSPA represents include disinfectants that kill germs in homes, hospitals and restaurants; air fresheners, room deodorizers and candles that eliminate odors; pest management products for home, lawn and garden, and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program, Product Care®, and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety and sustainability of their products.

<sup>2</sup> <https://monographs.iarc.fr/ENG/Monographs/vol77/mono77-9.pdf>

*“Exceptionally, agents for which the evidence of carcinogenicity is inadequate in humans but sufficient in experimental animals may be placed in this category when there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans.”<sup>3</sup>*

Accordingly, the coumarin monograph explicitly notes inter-species differences that lead to strong evidence of mechanism of carcinogenicity in experimental animals that does not operate in humans.

*Marked inter-species differences have been observed in the metabolism and toxicity of coumarin. The metabolism of coumarin involves two primary pathways, 7-hydroxylation and ring-opening to ortho-hydroxyphenylacetaldehyde. Coumarin is hepatotoxic in rat, mouse and dog, species in which ring-opening predominates. In contrast, humans and baboons, in which 7-hydroxylation is most evident, rarely show hepatotoxicity. Susceptibility to liver toxicity, in the rat at least, is also associated with extensive biliary excretion.*

Additionally, NTP evaluated the carcinogenicity and found it insufficient as there was only clear evidence in one species (mouse) and one sex (female) and did not meet the criteria for listing.<sup>4</sup> The preponderance of animal testing data has indicated that coumarin is not carcinogenic nor is there evidence of genotoxicity.

It is also notable that while humans have been exposed to both natural and synthetic forms of coumarin for much of recorded human history, there is no epidemiological evidence to indicate that coumarin is carcinogenic in humans.

In summary, CSPA believes there is insufficient scientific basis to support listing of coumarin as a potential carcinogen and respectfully requests that coumarin not be listed.

Sincerely,



Steven Bennett, Ph.D.  
Vice President, Scientific Affairs  
Consumer Specialty Products Association

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<sup>3</sup> <http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php>

<sup>4</sup> NTP (1993a). National Toxicology Program, U.S. Department of Health and Human Services. Toxicology and carcinogenesis studies of coumarin (CAS No. 91-64-5) in Coumarin F344/N rats and B6C3F1 mice (gavage studies). National Toxicology Program Technical Report Series No. 422.